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VacStent as an innovative approach in the treatment of anastomotic insufficiencies and leakages in the gastrointestinal tract – review and outlook

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ADMINISTRATIVE INFORMATION

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Conflicts of interest - M.M.H. is a Consultant to Möller Medical GmbH and is an inventor on a Patent to the VacStent. All other authors declare no conflict of interest.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 June 2024 and was last updated on 25 June 2024.

INTRODUCTION

Review question / Objective This review aims to evaluate the effectiveness and safety of the VacStent GI in treating gastrointestinal leaks compared to traditional methods such as self-expanding metal stents (SEMS) and endoscopic vacuum therapy (EVT), with a focus on success rates of leak closure, complication rates, and the overall impact on patient quality of life.

Rationale This study is necessary to evaluate the effectiveness and safety of the VacStent GITM in comparison to traditional treatments. By examining outcomes such as the success rate of leak closure, complication rates, and patient quality of life, the study seeks to determine whether the VacStent GITM offers a superior alternative for managing gastrointestinal leaks. Given the potential benefits of this innovative device, it is essential to establish its clinical efficacy through rigorous comparative analysis with established treatment modalities.

Condition being studied Anastomotic insufficiencies and leakages occur when the surgical connections between segments of the gastrointestinal tract fail to heal properly, resulting in the leakage of gastrointestinal contents into the surrounding abdominal cavity. This can lead to severe complications, including peritonitis, sepsis, prolonged hospitalization and need for recurrent surgery.
The incidence of anastomotic leaks varies depending on the type of surgery and the location of the anastomosis, but they are universally regarded as a serious complication with significant morbidity and mortality. Managing these leaks effectively is critical to improving patient outcomes and reducing healthcare costs.

METHODS

Search strategy As a structured method of gathering the data, we conducted a PRISMA conforming acquisition of suitable papers. We used the keyword "VACStent" and searched for current research via PubMed (Figure 2). We found 14 papers, in which the VacStent GITM was mentioned. We screened these papers by title and abstract alone, which led to the ex-clusion of six papers because they were no prospective studies. The remaining 8 papers were screened by full text. We continued to exclude 4 papers because the results of one prospective study were already included in another study we continued to select, one study only highlights preemptive usage of the VacStent GITM and two studies had a patient cohort of less than 10 patients. We decided to exclude the latter studies because we wanted to include studies with a comparable patient cohort than studies comparing EVT with SEMS. We compared these studies with a comprehensive review that compares SEMS versus EVT.

Participant or population Participants must be adults to ensure the applicability of findings to the adult population undergoing abdominal surgeries. Participants must have undergone abdominal surgery, specifically surgeries involving the gastrointestinal tract, which include but are not limited to colorectal surgeries, gastroesophageal surgeries and patients with confirmed anastomotic insufficiencies or leaks. This review includes participants of all genders and ethnicities. By focusing on these specific types of participants, the review aims to comprehensively evaluate the effectiveness and safety of different treatment modalities for anastomotic leaks in a diverse adult population undergoing abdominal surgery.

Intervention Not applicable.

Comparator Not applicable.

Study designs to be included Prospective studies.

Eligibility criteria Not applicable.

Information sources Electronic database (PubMed) and contact with authors.

Main outcome(s) The primary outcomes of the review include the success rate of leak closure and the complication rates associated with the treatments. The success rate of leak closure is defined as the proportion of patients in whom the anastomotic leak is successfully sealed without the need for additional surgical intervention. This will be evaluated at multiple intervals, such as immediately post-procedure, at discharge, and during follow-up visits (e.g., 1 month, 3 months, and 6 months post-procedure). The effect measure for this outcome is the proportion (percentage) of successful closures.

Quality assessment / Risk of bias analysis We only included prospective studies which met certain eligibility criteria to ensure comparability.

Strategy of data synthesis The data has been compiled and put together in two tables which are easy to understand.

Subgroup analysis Not applicable.

Sensitivity analysis Not applicable.

Country(ies) involved Germany.

Keywords VacStent; anastomotic insufficiency; endoscopic vacuum therapy; gastrointestinal leakage; covered stent; Esosponge.

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